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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/818,086	03/26/2001	Dale Baskin	7414.0043	2844

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EXAMINER

TUNG, JOYCE

ART UNIT PAPER NUMBER

1637

DATE MAILED: 05/27/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/818,086

Applicant(s)

BASKIN ET AL.

Examiner

Joyce Tung

Art Unit

1637

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 March 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-18 and 20-68 is/are pending in the application.
- 4a) Of the above claim(s) 51-67 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-18 and 20-68 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>3/02/2005</u> . | 6) <input type="checkbox"/> Other: _____ |

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Art Unit: 1637

DETAILED ACTION

The applicant's response to the Office action has been entered. Claims 1-18, 20-68 are pending. Claims 1-18, 20-50, and 68 are under examination.

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 12/03/2004 has been entered.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 1-18, are 20-68 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

- a. Claims 1-18, 20-25 and 68 are vague and indefinite because the phrase "directly sequencing". It is unclear what is the definition of the phrase. Clarification is required.
- b. Claims 26-50 are vague and indefinite because it is unclear whether or not the target polynucleotide are the same in the first reaction composition and the second reaction composition.

Art Unit: 1637

- c. Claims 26-50 are vague and indefinite because it is unclear how the target polynucleotide in the first reaction composition is detected since there is no detectable indicator in the first reaction composition. Clarification is required.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

5. Claims 1-18, 20-25 and 68 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Pritham et al. (J of Clinical Ligand Assay, 1998, Vol. (4), pg. 404-412) in view of Johnston-Dow et al. (6,103,465).

Pritham et al. disclose a rapid PCR method to monitor the amplification by detecting the fluorescent signal (See pg. 404, the abstract) involving using fluorescence probe (See pg. 405 column 2, second paragraph and pg 406 column 2 to pg. 409, column 1). The teachings of Pritham et al. are recited through out the limitations of claims 1-9, and 20-24, except that

Art Unit: 1637

Pritham et al do not disclose the sequencing method used to detect a specific target nucleic acid as recited in the limitations of claim 1.

Pritham et al. also do not indicate the source of the DNA sample used as listed in claims 10-18, and 25 in the method.

Johnston-Dow et al. disclose a method for typing HLA class I gene and the method involving DNA sequencing techniques (See the Abstract and column 9, lines 9-22). The method is to provide for the specific DNA sequencing of HLA-A, HLA-B and HLA-C (See column 3, lines 19-22). Johnston-Dow et al. also disclose that any source of human nucleic acid can be used, for example, blood and lymphoblastoid cell lines (See column 6, lines 9-14) as recited in the limitations of claims 10, and 25. Johnston-Dow et al. further indicate that HLA typing is performed routinely in connection with many medical indications, the study of auto-immune disease and the determination of susceptibility to infectious disease (See column 1, lines 57-62). This teaching suggests the limitations of claims 11-18 in that the pathogen will be from a virus, prokaryote and eukaryote, the presence of the given target polynucleotide indicates the presence of the genetic disease or a specific allele which can indicate serotype.

It would have been prima facie obvious to ^{one of} ~~an~~ ordinary skill in the art at the time of the instant invention to combine the teachings of Pritham et al. and Johnston-Dow et al. to carry out the method as claimed with a reasonable expectation of success. The motivation is that the teachings of Pritham et al. indicate that fluorescent monitoring of PCR provides qualitative and quantitative information in that the qualitative information includes purity and identity (See pg. 404, column 1, last paragraph) and rapid cycle PCR is an ideal technique for fluorescence monitoring because temperature gradients within samples are minimized (See pg. 404, column 2, second paragraph) and the method of Johnson-Dow et al. is applied to the locus-specific

Art Unit: 1637

nucleic acid amplification followed by sequence-specific detection of the amplified product for the DNA typing of HLA class I gene via DNA sequencing in that by sequencing the exons in both directions, the effect of sequencing errors on the assignment of HLA type is minimized and the method greatly reduces the number of reagents and the complexity of the sequencing protocols required (See column 9, lines 29-37).

The response argues that it would have been unpredictable at the time the invention was made whether an amplified product could be directly sequenced in the presence of a fluorescent indicator that is “a nucleic acid binding molecule” or in the presence of “an intercalating fluorescent indicator”. However, the limitations discussed herein are not in the claims. Moreover, the limitation “directly sequenced” is unclear what is the definition of the phrase as set forth in the section 3 above. In addition, the specification discloses that in certain embodiments, one does not actually sequence the amplification product from the reaction composition that includes the fluorescent indicator (See pg. 14, paragraph 042).

The response also argues that directly sequencing the amplification product in the presence of a fluorescent indicator that binds nucleic acid might have ~~been~~ been “obvious to try”. However, the limitation discussed herein is not in the claims. As indicated above, the limitation “directly sequenced” is unclear what is the definition of the phrase as set forth in the section 3 above.

The response further argues that the Applicant’s own work “direct sequencing of an amplification product in the presence of a fluorescent nucleic acid binding molecule” is not a reasonable expectation of success. However, the limitation discussed herein is not in the claims.

Art Unit: 1637

As indicated above, the limitation "directly sequenced" is unclear what is the definition of the phrase as set forth in the section 3 above. Thus the rejection is maintained.

Allowable Subject Matter

6. Claims 26-50 would be allowable if rewritten or amended to overcome the rejection(s) under 35 U.S.C. 112, 2nd paragraph, set forth in this Office action.

7. The following is a statement of reasons for the indication of allowable subject matter:

Concerning claims 26-50, no prior art has been found teaching or suggesting a method of determining the presence and sequence of at least one target polynucleotide in a sample comprising using two reaction compositions which combine to nucleic acid from the sample in which a first reaction composition comprises amplification primers specific to at least one target polynucleotide and a second reaction composition comprises a fluorescent indicator and amplification primer specific to at least one target polynucleotide.

The closest prior art is the reference of Wittwer et al. (6,174,670, issued Jan. 16, 2001). Wittwer et al. disclose methods of monitoring hybridization during polymerase chain reaction using two pairs of oligonucleotides and a nucleic acid binding fluorescent dye to monitor amplification of a selected template (See column 13, lines 62 to column 14, lines 29). However, Wittwer et al. do not disclose using two separate reaction compositions in a separate amplification reaction in which a first reaction composition comprises amplification primers specific to at least one target polynucleotide and a second reaction composition comprises a fluorescent indicator and amplification primer specific to at least one target polynucleotide.

Summary

8. No claims are allowed.

Art Unit: 1637

9. Any inquiries concerning this communication or earlier communications from the examiner should be directed to Joyce Tung whose telephone number is (571) 272-0790. The examiner can normally be reached on Monday-Friday from 8:00 AM-4:30 PM.

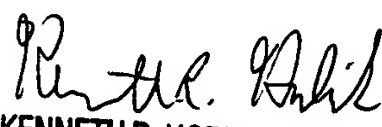
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached at (571) 272-0782 on Monday-Friday from 10:00 AM-6:00 PM.

8. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Art Unit 1637 via the PTO Fax Center located in Crystal Mall 1 using 571 273-8300. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989).

Joyce Tung

May 20, 2005




KENNETH R. HORLICK, PH.D
PRIMARY EXAMINER

5/25/05